# UNITED STATES PATENT AND TRADEMARK OFFICE

## BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte THOMAS GILCHRIST and DAVID MICHAEL HEALY



Appeal No. 2006-2713
Application No. 10/069,242

ON BRIEF

Before ADAMS, GREEN and LEBOVITZ, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1, 2, 4-7, 9, 10, 12-16, 18 and 19, which are all the claims pending in the application.

Claims 1, 12, 13, 18 and 19 are illustrative of the subject matter on appeal and are reproduced below:

1. A cell culture growth substrate adapted to sustain growth of living cells, said substrate comprising a water-soluble glass matrix which comprises at least a portion of its surface coated with living cells, wherein the water-soluble glass of said water-soluble glass matrix comprises at least one metallic ion or boron-containing compound capable of conferring antimicrobial protection or enhanced cell growth, or both.

12. The substrate of [c]laim 1, wherein said water-soluble glass matrix comprises water-soluble glass fibers.

13. The substrate of [c]laim 12, wherein said water-soluble glass fibers are sintered together to form a non-woven mat.

18. A method to encourage growth of living tissue by providing the substrate of claim 1.

19. The method of [c]laim 18, wherein said method includes a step of delivering metal ions or boron to an aqueous medium at a rate which maintains a concentration of metal ions or boron in said aqueous medium of not less than 0.01 parts per million and not greater than 10 parts per million.

The references relied upon by the examiner are:

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|---|---|---|
| Beaver et al. (Beaver) | 4,748,121 | May 31, 1988 |
| Ducheyne et al. (Ducheyne) | 5,811,302 | Sep. 22, 1998 |
| Gilchrist et al. (Gilchrist) | WO 98/54104 | Dec. 3, 1998 |

Burnie et al. (Burnie), "Controlled release glasses (C.R.G.) for biomedical uses," Biomaterials, Vol. 2, pp. 244-246 (1981)

## GROUNDS OF REJECTION

I. Claims 18 and 19 stand rejected under 35 U.S.C. § 112, second paragraph, as indefinite.

II. Claims 1, 2, 4-7, 9, 10, 12, 18 and 19 stand rejected under 35 U.S.C. § 103 as being unpatentable over the combination of Burnie and Gilchrist.[1]

III. Claims 1, 2, 4-7, 9, 10, 12, 18 and 19 stand rejected under 35 U.S.C. § 103 as being unpatentable over the combination of Burnie, Gilchrist and Beaver.

IV. Claims 13-16 stand rejected under 35 U.S.C. § 103 as being unpatentable over the combination of Burnie, Gilchrist and Ducheyne.

[1] We recognize the examiner's reliance on Beaver as "if necessary." Answer, page 4. We interpret this as an assertion of alternative grounds of rejection. Accordingly, for the purposes of our review, we have separated the grounds of rejection into their two separate alternatives.

V. Claims 13-16 stand rejected under 35 U.S.C. § 103 as being unpatentable over the combination of Burnie, Gilchrist, Beaver and Ducheyne.

We affirm rejections II and IV. We reverse rejection I. Having disposed of all claims on appeal we do not reach the merits of rejections III and V.

## DISCUSSION

### DEFINITENESS:

Claims 18 and 19 stand rejected under 35 U.S.C. § 112, second paragraph, as indefinite.

### CLAIM 18

The examiner finds (Answer, page 3), claim 18 is unclear because it recites a single step of providing a substrate. According to the examiner (id.), "[m]ore would be required to perform the process than merely providing the substrate of claim 1." In this regard, the examiner inquires (Answer, page 4), whether the substrate is combined with tissue that is then cultured, or whether other steps are carried out.

In response appellants explain (Brief, pages 5-6, emphasis removed),

> Claim 18 is a method for encouraging growth of living tissue by providing the substrate of [c]laim 1. The substrate of [c]laim 1 is a cell culture growth substrate, adapted to sustain growth of living cells, that comprises a water soluble glass matrix that comprises at least a portion of the surface coated with living cells, and wherein the water soluble glass of the water soluble glass matrix comprises at least one metallic ion or boron containing compound capable of conferring antimicrobial protection or enhanced cell growth, or both.

> As disclosed at page 3, lines 7-9, [a]ppellants state that the water soluble glass acts as a support or matrix for cell growth and hence the glass has utility in tissue engineering. As shown further, at page 4, lines 1-6, of the present application, the water soluble glass acts as a cell support matrix and will function as such in vivo (defined as in a living body). The result of this, as stated by [a]ppellants, is that the graft containing the water soluble glass can be used directly in vivo . . . to provide a temporary biodegradable scaffold which will encourage ingrowth of surrounding tissues . . . . Accordingly, the specification supports [c]laim 18 that is a method for encouraging growth of living tissue by providing the cell culture growth substrate as defined in [c]laim 1.

The examiner is not persuaded by appellants' explanation. According to the examiner (Answer, bridging sentence, pages 8-9), "claims per se must be clear and definite without relying on the specification for definiteness and clarity." We disagree. Claims are in compliance with 35 U.S.C. § 112, second paragraph, if "the claims, read in light of the specification, reasonably apprise those skilled in the art and are as precise as the subject matter permits." Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1385, 231 USPQ 81, 94-95 (Fed. Cir. 1987).

For the foregoing reasons, it is our opinion that "one skilled in the art would understand the bounds of the claim when read in light of the specification." Miles Laboratories, Inc. v. Shandon, Inc., 997 F.2d 870, 875, 27 USPQ2d 1123, 1126 (Fed. Cir. 1993). Accordingly, we reverse the rejection of claim 18 under 35 U.S.C. § 112, second paragraph.

CLAIM 19

As discussed above, claim 1 is drawn to a cell culture growth substrate, adapted to sustain growth of living cells, that "comprises a water soluble glass matrix that comprises . . . at least one metallic ion or boron-containing compound capable of conferring antimicrobial protection or enhanced cell growth, or both." We note with interest that the claim 1 requires a water soluble glass matrix that comprises at least one metallic ion or boron-containing compound. Claim 18 is drawn to a method for encouraging growth of living tissue by providing the substrate of [c]laim 1. Claim 19 depends from and further limits claim 18 to include a step of delivering metal ions or boron to an aqueous medium.

According to the examiner (Answer, page 4), the term "aqueous medium" as it appears in line 2 of claim 19 lacks antecedent basis. The examiner appears to be confused. Claim 19 depends from and further limits claim 18 to include the step of delivering metal ions or boron to an aqueous medium. This step did not appear in the preceding claims, because it was not until claim 19 that such an additional step was required.

The examiner is also "uncertain as to the relationship of the aqueous medium to the tissue and substrate in claim 18, and as to steps used to deliver the metal ions or boron." Id. It would appear from reading the claims as a person of ordinary skill in the art that an aqueous medium would be the medium in which the tissue is grown. As to the steps for delivery of metal ions or boron, we note that claim 1 requires that the water soluble glass matrix comprise at least one metallic ion or boron-containing compound. Therefore, reading claim

19 as a person of ordinary skill in the art we understand that metal ions or boron will be delivered to the aqueous medium as the water soluble glass matrix dissolves in the aqueous environment.

We remind the examiner that claim language must be analyzed "not in a vacuum, but always in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary skill in the pertinent art." In re Moore, 439 F.2d 1232, 1235, 169 USPQ 236, 238 (CCPA 1971). For the foregoing reasons we reverse the rejection of claim 19 under 35 U.S.C. § 112, second paragraph.

OBVIOUSNESS:

The combination of Burnie and Gilchrist:

Claims 1, 2, 4-7, 9, 10, 12, 18 and 19 stand rejected under 35 U.S.C. § 103 as being unpatentable over the combination of Burnie and Gilchrist. Appellants provide arguments for the following two claim groupings: I. claims 1, 2, 4-7, 9, 10 and 12; and II. claims 18 and 19. We, therefore, limit our discussion to representative claims 1 and 18. Claims 2, 4-7, 9, 10 and 12 will stand or fall together with claim 1. Claim 19 will stand or fall together with claim 18. In re Young, 927 F.2d 588, 590, 18 USPQ2d 1089, 1091 (Fed. Cir. 1991).

According to the examiner (Answer, bridging paragraph, pages 4-5), Burnie disclose the use of a water-soluble controlled release glass (CRG) substrate in monolayer cell culture, and in vivo. In this regard, the examiner finds that the only difference between Burnie's water-soluble glass and

appellants' is that appellants' glass comprises "a metallic ion or boron-containing compound capable of conferring antimicrobial protection or enhanced cell growth, or both." Answer, page 5.

The examiner relies on Gilchrist to make up for the deficiency in Burnie. According to the examiner, Gilchrist disclose a water-soluble glass fibre containing a boron-containing compound and metal ions, including those with anti-microbial activity. Id.

Based on this evidence, the examiner concludes (id.), it would have been obvious to substitute the water-soluble glass of Burnie with that of Gilchrist to have a substrate for cell growth in culture as well as in vivo, which has the added advantage of antimicrobial protection.

CLAIM 1

In response, appellants point out that Burnie's CRG does not contain a metal ion or boron-containing compound. Brief, pages 7-8. In addition, while appellants agree that Gilchrist describes water-soluble glass fibers containing boron and/or silver ions, Gilchrist does not "disclose or suggest that the [fiber] materials . . . would be suitable for use as cell culture growth substrates." Brief, page 8. According to appellants (Brief, page 9), "there is no showing that would support a conclusion that one of ordinary skill would have been inclined to modify . . . [Burnie], by substituting the water soluble glass composition of . . . [Gilchrist]."

As appellants explain (Brief, pages 5-6, emphasis removed),

> As disclosed at page 3, lines 7-9 [of their specification], [a]ppellants state that the water soluble glass acts as a support or matrix for cell growth and hence the glass has utility in tissue engineering. As shown further, at page 4, lines 1-6, of the present application, the water soluble glass acts as a cell support matrix and will function as such in vivo (defined as in a living body). The result of this, as stated by [a]ppellants, is that the graft containing the water soluble glass can be used directly in vivo . . . to provide a temporary biodegradable scaffold which will encourage ingrowth of surrounding tissues . . . .

We find appellants statement of the scope of the claim to be consistent with the specification. See Specification, page 4, lines 4-11. Accordingly, by explaining that the water-soluble glass "provides a temporary biodegradable scaffold which will encourage ingrowth of surrounding tissues," we understand appellants' use of the term "coated" in claim 1 to be in the context of the ingrowth of surrounding tissues, in addition to the alternative embodiments wherein for example the glass is "pre-seeded" prior to implantation (specification, page 4, lines 8-11), or coated with living cells. Cf. appellants' claim 2, which depends from and further limits the substrate of claim 1 to a substrate that "is coated with living cells."

In this regard, we note that appellants' list orthopedics among the potential tissue engineering applications for their water-soluble glass. Specification, page 2. In addition, we note that according to appellants' specification (page 4, lines 31-32), the water-soluble glass matrix may be in the form of fibres. Burnie teaches a water-soluble glass in the form of a fibre (page 244, column 2, third full paragraph), with application in orthopedics. In addition, Burnie reports that when used in orthopedics no adverse effects were observed and new bone formation filled the "gap" between the old bone and the shrinking

the water-soluble glass implant. Burnie, page 245, first column, first paragraph under "RESULTS." In other words, Burnie teaches that the water-soluble glass provided a temporary biodegradable scaffold which encouraged ingrowth of surrounding tissues. The only response articulated by appellants with regard to Burnie is that the reference fails to teach a water-soluble glass that comprises a boron-containing compound or a metal ion. But Gilchrist teaches this glass, in the form of a fibre. See e.g., Gilchrist, abstract. Also, while Gilchrist is primarily focused on the production of water-soluble glass fibres, the reference discloses that "[t]he fibres are suitable for orthopaedic implants and tissue engineering applications." Id., page 17, lines 19-21. So while appellants' argue that Gilchrist is concerned with the manufacture of water-soluble glass fibres (see e.g., Brief, bridging paragraph, pages 8-9), we note that Gilchrist discloses that these fibres are to be used in orthopaedic applications, e.g., those described by Burnie. Accordingly, we are not persuaded by appellants' arguments.

On reflection, we find the weight of the evidence falls in favor of the examiner. "A prima facie case of obviousness is established when the teachings from the prior art itself would appear to have suggested the claimed subject matter to a person of ordinary skill in the art." In re Bell, 991 F.2d 781, 782, 26 USPQ2d 1529, 1531 (Fed. Cir. 1993) (quoting In re Rinehart, 531 F.2d 1048, 1051, 189 USPQ 143, 147 (CCPA 1976)). For the foregoing reasons we affirm the rejection of claim 1 under 35 U.S.C. § 103 as being unpatentable over the combination of Burnie and Gilchrist. As set forth above, claims 2, 4-7, 9, 10 and 12 fall together with claim 1.

CLAIM 18

According to appellants, the combination of references do not suggest the claimed method. Brief, page 10. We disagree. As set forth above, claim 18 is drawn to "[a] method to encourage growth of living tissue by providing the substrate of claim 1." Also as set forth above, Burnie teaches a water-soluble glass in the form of a fibre (page 244, column 2, third full paragraph), with application in orthopedics. Burnie reports that when used in orthopedics, no adverse effects were observed and new bone formation filled the "gap" between the old bone and the shrinking the water-soluble glass implant. Burnie, page 245, first column, first paragraph under "RESULTS." In other words, Burnie teaches that the water-soluble glass provided a temporary biodegradable scaffold which encouraged ingrowth of surrounding tissues. We note that these tissues were living. As discussed above, it is our opinion that a person of ordinary skill in the art would have found it prima facie obvious to modify the glass taught by Burnie with the glass taught by Gilchrist[2], and use the modified glass in orthopedic applications to encourage the growth of living tissue as taught by Burnie for its anti-microbial advantages.

On reflection, we find the weight of the evidence falls in favor of the examiner. Accordingly, we affirm the rejection of claim 18 under 35 U.S.C. § 103 as being unpatentable over the combination of Burnie and Gilchrist. As set forth above claim 19 falls together with claim 18.

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[2] See e.g., Gilchrist, page 15, line 10, wherein Gilchrist teach a glass comprising a metal ion that exhibits anti-microbial activity.

The combination of Burnie, Gilchrist, and Ducheyne:

Claims 13-16 stand rejected under 35 U.S.C. § 103 as being unpatentable over the combination of Burnie, Gilchrist and Ducheyne. Appellants do not separately argue any of claims 13-16. Therefore, we limit our discussion to representative claim 13. Claims 14-16 will stand or fall together with claim 13. In re Young, 927 F.2d 588, 590, 18 USPQ2d 1089, 1091 (Fed. Cir. 1991).

As we understand the statement of the rejection, the examiner relies on the combination of Burnie and Gilchrist as set forth above with regard to claims 1, 2, 4-7, 9, 10 and 12. This combination, however, fails to teach that the glass fibers are sintered together to form a mat. To make up for this deficiency, the examiner relies on Ducheyne. According to the examiner (Answer, page 8), Ducheyne discloses "sintering glass particles (powder) and binder in a slurry to form a porous substrate for cell culture." Accordingly, the examiner finds that it would have been obvious to modify the glass taught by the combination of Burnie and Gilchrist to form a sintered non-woven mat.

For their part, appellants rely on their arguments with regard to the rejection of claim 1 in view of the combination of Burnie and Gilchrist. Brief, page 12. In this regard, appellants assert (id.), "if one of skill in the art were to combine the teachings of Ducheyne et al., relating to sintering, with any of the other cited references, [a]ppellants' claimed invention would not be obtained." We disagree. As discussed above, we find that the subject matter set forth in appellants' claim 1 would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made in view of the combination of

Burnie and Gilchrist. As for the subject matter of claim 13 on appeal, appellants do not provide an argument against the combination of Burnie, Gilchrist and Ducheyne. Accordingly, we affirm the rejection of claim 13 under 35 U.S.C. § 103 as being unpatentable over the combination of Burnie, Gilchrist and Ducheyne. As set forth above, claims 14-16 fall together with claim 13.

The combination of Burnie, Gilchrist and Beaver:

Having disposed of claims 1, 2, 4-7, 9, 10, 12, 18 and 19 under 35 U.S.C. § 103 as being unpatentable over the combination of Burnie and Gilchrist, we do not reach the merits of the rejection of these same claims under 35 U.S.C. § 103 as being unpatentable over the combination of Burnie, Gilchrist and Beaver.

The combination of Burnie, Gilchrist, Beaver and Ducheyne:

Having disposed of claims 13-16 under 35 U.S.C. § 103 as being unpatentable over the combination of Burnie, Gilchrist and Ducheyne, we do not reach the merits of the rejection of these same claims under 35 U.S.C. § 103 as being unpatentable over the combination of Burnie, Gilchrist, Beaver and Ducheyne.

## APPELLANTS' SECONDARY CONSIDERATIONS

According to appellants (Brief, page 11), their results "were unexpected and surprising" because the metallic ions of "[a]ppellants' claimed invention . . . are generally considered to be toxic to the human body. However addition of the metallic ions to the water-soluble glass substrate . . . stimulated, rather than disrupted, cell growth." Appellants' comments have been considered but were not found persuasive. As the examiner points out (Answer, page 11), Gilchrist discloses "using the metal-containing water soluble glass as an implant, for tissue engineering and to release metals at a wound site, suggest[ing] that toxicity is not of a sufficient level to make the glass unsuitable for cell growth." In this regard, we note that there is no requirement for a particular concentration of metal ion, or boron-containing compound in claims 1 and 18. In all, we are not persuaded by appellants' arguments of unexpected results.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

Donald E. Adams )
Administrative Patent Judge )
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Administrative Patent Judge ) APPEALS AND
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